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IMPLEMENTATION GUIDE

for use with

10 CFR PART 830.120

QUALITY ASSURANCE

FINAL GUIDE - FOR UNLIMITED USE AND DISTRIBUTION

FORWARD

This Department of Energy Implementation Guide is approved for use by the Division of Nuclear Safety Policy, Office of Nuclear Policy and Standards (EH-62) and is available for use by all DOE components and their contractors.

Beneficial comments (recommendations, additions, deletions, and any pertinent data) that may improve this document should be sent to:

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Implementation guides are used to identify Government and non-Government standards that DOE finds acceptable for implementing the Department's requirements. Applicable standards are included as a list following each section of this guide. In addition, each section includes a list of references which provide other sources of information.

ACKNOWLEDGMENTS

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Section I, INTRODUCTION

The department of Energy and its contractors are responsible for basic and applied research; product development; and designing, constructing, operating, modifying, and decommissioning DOE facilities and sites to effectively accomplish DOE's mission and objectives. This work must be accomplished while minimizing potential hazards to the public, site or facility workers, and the environment. The criteria of 10 CFR Part 830.120 prescribe a comprehensive management system for DOE work. The successful application of the management system should embrace the philosophy described in DOE/HR-0066, Total Quality Management Implementation Guidelines. The principles described in DOE/HR-0066 are applied in practice through the application of the criteria of 10 CFR Part 830.120.

Section II, APPLICATION

This implementation guide provides information concerning the use of current principles and practices to establish and implement effective management programs. Approved management programs based on DOE 5700.6C will meet the requirements of 10 CFR Part 830.120.. 10 CFR Part 830.120 requires the preparation of an implementation plan which describes the schedules, milestones, and activities necessary to implement the regulation. This guide, along with the regulation, will aid the development of implementation plans.

This guide explains each of the ten criteria contained in 10 CFR Part 830.120. The criteria are interrelated and include requirements for managing, achieving, and assessing quality that result in improved safety and reliability of the Department's products and services.

Section III, DISCUSSION

Quality is a description of excellence. The quality attained in a product or service is described by the extent to which that product or service satisfies the requirements, needs, and expectations of the customer. The attainment of quality is the responsibility of each member of an organization, including top management. The quality management program described in 10 CFR Part 830.120 provides a results-oriented management system that focuses on the customer efficient through constant process improvement. Senior management

should require and cultivate the integration of quality into all levels of the organization.

Section IV, GUIDELINES

1. PROGRAM

1.1 Introduction

The principle factor reflecting the performance of an organization is the quality of its products and services. Criterion 1 requires that an organization develop and maintain and effective management system with the goal of ensuring safe, reliable products and services that meet or exceed the customer's requirements, needs, and expectation. The management system should include the methods for managing, performing, and assessing the adequacy of work, including work assigned to parties outside the organization.

The management system should focus on accomplishing the mission as outlined in the organization's strategic plan. The management system applies to every component and employee of the organization, and includes the organizational structure, functional responsibilities, levels of authority, and interfaces.

1.2 Responsibilities

Management retains the primary responsibility and is accountable for the scope and implementation of the management system. However, every individual in the organization is responsible for achieving quality in his or her activities. Management should promote effective achievement of performance objectives through the:

- establishment of task assignments:
- identification of lines of communication; and
- determination and provision of the necessary resources and environment to accomplish the required activities.

Management should ensure that all personnel understand and implement the management system.

1.3 Graded Approach

The scope and depth of the management system's application of requirements to a specific activity should be determined by the use of a grading process. The grading process provides the flexibility to design controls that best suit the facility or activity. The graded approach process should determine the appropriate level of effort

necessary to attain and document the requirements established through the consideration of prescribed factors. This process is based on a prescribed facility-specific or activity-specific factors such as the:

- o level of risk;
- o age, status, and condition of a facility or process;
- o history of problems at a site or facility
- o adequacy of existing safety documentation; and
- o complexity of products or services involved.

The graded approach process should not be sued to obtain relief from the requirements of 10 CFR Part 830.120.

1.4 Applicable Standards

The following consensus standards provide acceptable methods for implementing many of the requirements of 10 CFR Part 830.120. No single standard fully meets all of the requirements. The principles, recommended approaches, and applications contained in these standards may be sued in conjunction with 10 CFR Part 830.120 to develop an effective management system to achieve quality.

1. International Standard ISO 9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements-Guidelines, Section 4, "Management Responsibility," and Section 5, "Quality System Principles."

2. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research.

3. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 1, "Organization," and 2, "Quality Assurance Program;" the supplementary requirements contained in Supplement 1S-1; and the nonmandatory guidance contained in Appendix 1A-1.

1.5 References

1. International Atomic Energy Agency (IAEA) Safety Guide 50-SG-QA1, to be issued, Establishing and Implementing a Quality Assurance Programme.

2. ANSI/ASQC E44-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.1, "Quality Management and Organization," Part A-2, "Quality System and Description," and Part A. Section 2.7, "Quality Planning."

3. DOE RW-0333P, dated December 18, 1992, Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program.

4. USNRC NUREG-0800, Revision 0, dated August 1990, Standard Review Plan, Section 17.3, "Quality Assurance Program Description."

5. ASME NQA-2-1989, Quality Assurance Requirements for Nuclear Facility Applications.

6. ASME NQA-3-1989, Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories.

7. Institute of Electrical and Electronics Engineers Standard, IEEE 730-1984, IEEE Standard for Software Quality Assurance Plans.

8. American Nuclear Society Standard ANS-3.2, Quality Assurance Requirements for Operating Nuclear Power Plants.

2. PERSONNEL TRAINING AND QUALIFICATION.

2.1 Introduction

A fundamental requirement for effective accomplishment of any mission is that all personnel be capable of performing their assigned tasks. Qualification and training programs ensure that the required capabilities are achieved and maintained by personnel.

2.2 Responsibilities

Management should commit resources to facilitate the training and qualification processes, provide qualification and training requirements for personnel in their organizations, and ensure that personnel hired or transferred into positions meet the appropriate requirements. Each level of the organization should adequately describe their training and qualification processes. These descriptions should include requirements, interfaces, training methods, and training responsibilities and duties of line and training organizations.

2.3 Qualification of Personnel

Policies and procedures that describe personnel selection requirements should b e established for each position. These should include the minimum applicable requirements for education, experience, and physical condition.

Management should determine that personnel are suitable qualified to accomplish their assigned tasks. Personnel may be qualified by:

- considering previous experience, education, and training;
- demonstrating and testing to verify previously acquired skills; or
- completing a training or qualification program.

2.4 Training

Training should provide knowledge of the correct processes and methods to accomplish assigned tasks. It should also provide an understanding of the fundamentals of the work, the context within which the work is performed, and the reasons for any special work requirements.

Training goals, lesson plans, and other training materials should be consistently developed, reviewed by subject matter experts, approved by management, and used to effectively deliver training. Training materials should be controlled to ensure that the latest approved versions are used.

Training effectiveness should be constantly monitored. Worker performance should be evaluated to ensure that the training program conveys all required knowledge and skills. Feedback from personnel performance former trainees, and supervisors should be used to determine effectiveness of training. The results of these evaluations should be used as the basis for improving the training program.

Training usually falls within three categories: project specific, site specific, and institutional.

Project-specific training should impart the knowledge required for the employee to get practice his/her knowledge or skills toward the successful completion of the mission. This training might include mission goals, methods, requirements, process metrics, and skills. Project specific training requirements should be defined by project management and workers.

Site-specific training should convey the safety, security, and operations knowledge required to enter a specific site. The site owner is responsible for defining training requirements and ensuring that the training is administered.

Institutional training should convey general information about the organization's mission, vision, goals, and management system. It may also include general knowledge or skills training.

2.5 Training Plans

Training plans should be prepared for all personnel. The content of initial training plans should prepare personnel to perform the job. The content of continuing training plans should maintain and promote progressive improvement in incumbent job performance. Training plans may also provide employee satisfaction and interest for further self enhancement., In this way, training plans can be valuable in motivating personnel to develop enhanced technical, managerial, or other skills capabilities, and in tracking and documenting such development.

In the generation of a training plan, the manager and worker should consider all types of available training. Current facility, site, or organization procedures; technical and professional references; and past organization/industry experience should also be used to identify training plan content.

2.6 Instructors

Instructors may be training providers or qualified members of the organization requiring training. Instructors should posses technical knowledge, experience, and development and instructional skills. Instructor training should be based, in part, on the results of instructor evaluations and training on new methods and equipment.

2.7 Applicable standards

The following consensus standards provide acceptable methods for implementing many of the requirements of criteria 2. No single standard fully meets all of the requirements. The principles, recommended approaches, and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the development of an effective personnel qualification and training program.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.18, "Training."

2. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality system Elements-Guidelines, Section 18.1, ":Training" and Section 18.2, "Qualification."

3. DOE-STD-1008-92, DOE Guideline, dated July 1992, Guide to Good Practices for On-Training of Technical Staff and Managers.

4. DOE-STD-1012-92, DOE Guideline Dated July 1992, Guide to Good Practices for On-The-Job Training.

5. DOE-STD-1005-92, DOE Guideline Dated July 1992, Guide to Good Practices for Developing Learning Objectives.

6. DOE-STD-1006-92, DOE Guideline Dated July 1992, Guide to Good Practices: Evaluation Instrument Examples.

7. DOE-STD-1007-92, DOE Guideline Dated July 1992, Guide to Good Practices for Teamwork Training and Diagnostic Skills Development.

8. DOE-STD-1011-92, DOE Guideline Dated July 1992, Guide to Good Practices for the Design, Development, and Implementation of Examinations.

9. NE-STD-1002-91, dated November 1991, Guide to Good Practices for Training and Qualification of Chemical Operators.

10. NE-STD-1003-91, dated November 1991, Guide to Good Practices for Training and Qualification of Maintenance Personnel.

11. ANSI/ANS-3.1-1987, American National Standard for Selection, Qualification and Training of Personnel for Nuclear Power Plants.

12. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Supplements 2S-1,. 2S-2, 2S-3, AND 2S-4, and appendices 2A-1, AND 2A-2.3.

2.8 References

1. DOE/NE-0101T, TAP-1 - Training Program Manual, U.S. Department of Energy, Assistant Secretary for Nuclear Energy, July 1991.

1. DOE/NE-0102T, TAP-2 - Performance-based Training Manual, U.S. Department of Energy, Assistant Secretary for Nuclear Energy, July 1991.

1. DOE/NE-0103T, TAP-3 - Training Program Support Manual, U.S. Department of Energy, Assistant Secretary for Nuclear Energy, July 1991.

4. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research, Page 6 - 7.

5. IAEA Safety Guide 50-SG-QA-2, to be issued, Establishing and Implementing a Quality Assurance Programme, Training Section, and Annex 2 requirement on training.

For some specific skilled work tasks, useful practical principles and applications are contained in standards and guides prepared by industry and professional organizations such as the American Society of Mechanical Engineers (ASME), the American Welding Society (AWS), the Institute for Nuclear Power Operations (INPO), the American Society for Testing Materials (ASTM), and the Electric Power Research Institute (EPRI). Particularly useful examples include the qualification requirements in the American Society of Nondestructive Testing (ASNT) Standard ASNT-TC-IA, and in the ASME Boiler and Pressure Vessel Code, Sections V and IX.

3. QUALITY IMPROVEMENT

3.1 Introduction

Quality improvement is based on the premise that all work activities can be planned, performed, measured, and improved. Management is responsible for building a culture in which improvement is continuous and an integral part of the organization. In promoting that culture, management should encourage the development and exploration of new ideas. The continuous improvement effort should increase worker awareness of the importance of quality and emphasize enhanced product and process safety and reliability. It should also promote a work environment in which all personnel will readily identify nonconforming items and potential areas for improvement.

Management policy for continuous improvement should encourage the development and exploration of new ideas for improvement. Management policy for continuous improvement should be documented and communicated to all levels of the organization. The policy should make clear that the responsibility for improvement rests with each individual and organizational element and cannot be delegated to a particular person or group within the organization.

The continuous improvement approach focuses on problem prevention, corrective action, and performance improvement rather than relying on post-process inspection to prevent defective items from reaching customers. Process performance should be continuously measured and evaluated to identify improvement opportunities. Each manager is responsible for managing process quality within their organization. Each worker should know how their process contributes to the strategic goals of the organization.

3.2 Continuous Improvement

Process performance should be continuously evaluated to identify actions that can be taken to improve output quality. These evaluations may be based on quantitative and/or qualitative information obtained from monitoring process performance indicators and from management and independent assessments. The areas of performance that most directly affect the process's ability to meet customer requirements and expectations should receive the greatest emphasis in process improvement. Any failures to meet customer requirements or expectations should be identified, corrected, and prevented from recurrence.

One approach to process improvement is the Plan-Do-Check-Act (PDCA) cycle. It is a formalized technique for referring to the continuous process of studying a work process and finding new ways to improve performance. The PDCA cycle is an

ongoing pursuit of the planning, implementing, and evaluating of process improvements. Workers should be empowered through training to operate processes, identify process deficiencies, develop improvement approaches, implement solutions, and evaluate process improvements. Open communications across all levels of the organization are essential for continuous improvements.

The "Plan" phase should define what the process is required to accomplish. The process should be designed to be results-oriented and based on desired identification, desired output, process steps, process capability, performance indicators, resources, and process baseline.

During the "Do" pr performance phase, work is accomplished to produce goods or services for the customer. Process improvements are implemented.

The "Check" phase should measure the process operation. Process performance indicators should be monitored and results examined for indications of required adjustments. The process should be operating to a performance baseline and the workers should be alert for problems or improvement opportunities.

The "Act" phase should determine how the process is working and if further process refinements are required. The qualitative and quantitative data gathered is analyzed and results compared to the desired process results and to results from similar processes. Trends in productivity and quality can be identified. If the need for further process modifications are indicated, concepts should be generated to feed to the planning phase for further consideration.

3.3 Applicable Standards

There are no directly applicable standards on the subject of Quality Improvement: However, there are some reference materials that provide useful information on the approach, and there are standards that cover specific limited areas such as statistics, root cause analysis, or the control of nonconforming materials. Examples of those documents are listed below under references.

3.4 References

1. Malcolm Baldridge National Quality Award Criteria, U.S. Department of Commerce Technology Administration, National Institute of Standards and Technology, 1993.

2. Quality Improvement Tools, Juran Institute, Wilton, CT, 1989.

3. DOE Student Training Manual, Criterion 3, Quality Improvement Course, Handbook of Concepts, Tools, and Techniques.

4. DOE-STD-1048-92, Dated December 1, 1992, Performance Indicators Guidance Document.

5. DOE-NE-STD-1004-92, Dated February 1, 1992, Root Cause Analysis Guidance Document.

6. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality system Elements-Guidelines, Section 14, "Nonconformity," and Section 15, "Corrective Action."

7. IAEA Safety Guide 50-SG-QA12, to be issued, Nonconformance Control and Corrective Action.

8. ANSI/ASQC Standard E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.10, "Quality Improvement."

9. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 15, "Control of Nonconforming Items," with Supplement 15S-1, and Basic Requirements 16, "Corrective Actions."

10. DOE/HR-0066, dated December 1993, Total Quality Management Implementation Guidelines.

4. DOCUMENTS AND RECORDS

4.1 Introduction

Documents and records are required to manage, perform, and assess work. Management should identify any documents which must be controlled and records which must be generated, and should commit the resources necessary to accomplish the document and record requirements.

4.2 Documents

Documents may be required by organizations, projects, or programs to control policy, administrative, or technical information. A document may describe work to be done, data to be used at different locations or by different people, or, in changing situations, data that is controlled from time to time for reference purposes. A document control process should establish requirements to release documents for distribution, identify recipients, specify actions to be taken with existing documents when revisions are released for distribution or documents are canceled, and identify unique revisions and copies.

Document control requirements should be defined by each organizational unit. Although the actual process may be supplied internally or externally, the organizational unit is responsible for ensuring that their requirements are being met.

4.3 Records

A record contains information that is retained for its expected future value. Records should be sufficient to support technical and regulatory decisions. Records and documents may be electronically stored, written or printed, microfilm photographs, radiographs, or laser disks.

Records are compiled into a records management system that ensures appropriate records are maintained. The records system should include provisions for retention, protection, preservation, changing, traceability, accountability, and retrievability or records. While in storage, records should be protected from damage, loss, and deterioration. Evidentiary records should have appropriate procedures controlling media type, chain of custody, and confidentiality.

For records that require electronic processing control, the hardware and software required to maintain and access the records should be maintained and controlled to ensure that the records remain usable. These records include information recorded on magnetic media and optical disks.

The National Archives and Records Administration (NARA) has final authority for approving the disposition of Government records. NARA publishes the General Records Schedule (GRS), and approves DOE unique records schedules. All records management systems should have schedules for records retention and disposition in accordance with the requirements of NARA and DOE 1324.2 (latest issue), "Records Disposition." Records management systems should address the requirements of DOE 1324.5 (latest issue), "Records Management Program." Applicable standards may differ in records management terminology from the NARA requirements. Care should be taken to ensure that the requirements of NARA, applicable standards, and any additional statutory requirements are met. Records retention times may also be included in contractual requirements.

4.4 Applicable Standards.

The following consensus standards provide acceptable methods for implementing many of the requirements of Criterion 4. No single standard fully meets all of the requirements. The principles and recommended approaches and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the establishment and implementation of an effective document control and records management system.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.5, "Document Control," and Section 4.16, "Quality Records."

2. ISO-9002-1987 (ANSI/ASQC Q92-1987), Quality Systems - Model for Quality Assurance in Production and Installation, Section 4.5, "Document Control," Section 4.16, "Quality Records."

3. ISO-9003-1987 (ANSI/ASQC Q93-1987), Quality Systems - Model for Quality Assurance in Final Inspection and Test, Section 4.3, "Document Control," and Section 4.10, "Quality Records."

4. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements-Guidelines, Section 17, "Quality Documentation and Records."

5. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 6, "Document Control," and 17, "Quality Assurance Records," Supplements 6S-1 and 17S-1, and Appendix 17A-1.

4.5 References

1. USNRC Regulatory Guide 1.28, dated August 1985, Quality Assurance Program Requirements (Design and Construction), Table 1, "Retention Times for Lifetime and Nonpermanent Records."

2. Title 44 United States Code (U.S.C.) Chapter 21, National Archives and Records Administration (NARA), which establishes certain authorities in the Archivist of the United States for the acceptance and preservation of records of a Federal agency.

3. Title 44 U.S.C. Chapter 33, Disposal of Records, which establishes the procedural requirements for obtaining authority from the Archivist for the disposal of Departmental records.

4. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research, Page 8.

5. IAEA Safety Guide 50-SG-QA-2, to be issued, Document Control and Records.

5. WORK PROCESSES

5.1 Introduction

A work process includes all activities involved in performing defined tasks to achieve an objective. Work processes may include such activities as planning, scheduling, accounting, project management, design, analysis, fabrication, procurement, construction, installation, testing, operation, modification, maintenance, and decommissioning. The work process is a planned mix of people, equipment, environmental conditions, supply, management support, resources, and requirements. Each of these elements contributes to achieving process goals.

5.2 Management Responsibility

Managers should routinely be involved in work processes to ensure that criteria for acceptable work performance are clearly defined. The manager is responsible for setting requirements and policies which control the conditions under which the work process is required to function. These conditions should be considered as an element affecting product and service output and quality.

The manager is responsible for planning and designing the work process. The required goals should be known in order to plan for the work processes. Work should be performed to prescribed standards, procedures, or instructions of a detail commensurate with the complexity and importance of th work. When possible, administrative controls should be simplified to minimize the impact of controls on the worker. Personnel performing a process should be included in process improvement activities. The work process should be designed to produce the desired quantity and quality of output.

The manager is responsible for placing qualified personnel in positions to accomplish work and training them in the requirements of the job. Workers should be trained to new conditions if the work process is changed.

5.3 Worker Responsibility

Workers are responsible for the quality of their own work. Workers should set goals for doing the work correctly the first time and contribute to improved work processes.

Workers should be considered as prime resources concerning the various aspects of their process. They understand how the process works and how metrics can best be applied. They are first line contact with both customers and suppliers and possess first hand knowledge of the products and services being supplied to and by their process.

5.4 Work Process Documents

The manager should clearly identify authorities, responsibilities, and interfaces, both internal and external regarding the work process in appropriate work process documents. Policies, procedures, goals, plans and any other information affecting a process should be clearly communicated to the personnel working within that process.

Applicable work process documents should be readily accessible to the worker. Work process documents should be based on the skills of th workers using them and on the complexity and importance of the work. Work process documents should include any requirements for special processes which are highly dependent on the control of the process or the skill of the operator, and for which the quality of the product cannot be readily determined by inspection or test.

Work process documents should address such process elements as methods to prevent the use of incorrect or defective items and to ensure items requiring traceability are identified and controlled. Documents should describe methods controlling packaging, shipping, receiving, storage, handling, cleaning, and preservation of items to prevent damage, loss, or deterioration.

5.5 Applicable Standards

The following consensus standards provide acceptable methods for implementing many of the requirements of Criterion 5, Although none of the standards fully meets all of the requirements. The principles and recommended approaches and practices contained in these standards may be used in conjunction with 10 CFR Part 830.120 in developing effective work process controls.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.9, "Process Control."

2. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements - Guidelines, Section 10.0, "Quality in Production," and Section 11.0, "Control of Production."

3. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 8, "Identification and Control of Items;" 9, "Control of Processes;" 13, "Handling, Storage, and Shipping;" and 15, "Control of Nonconforming Items;" and Supplements 9S-1, 12S-1, and 13S-1.

4. DOE/RW/0333P, dated December 18, 1992 Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program, Section 9, "Control of Special Processes."

5.6 References

1 DOE Student Training Manual, dated April 7, 1993, Management in the Work Process.

2. NUREG 1293, Revision 0, dated January 1989, Quality Assurance Guidance for Low Level Waste Disposal Facility, Section 9, "Control of Processes."

3. ANSI/ASQC Standard E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.8, "Quality Implementation of Work Processes."

6. DESIGN

6.1 Introduction

Definition, control, and verification of design is necessary to ensure that systems, structures, and components fulfill contractual requirements and customer expectation. Design work should be based on sound engineering and scientific principles. A formal design process should be established which provides control of design inputs, outputs, verification, configuration and design changes, documentation, records, and technical and administrative interfaces.

Systems, structures, and components important to safety should be subject to more stringent operational criteria and verification requirements than those not important to safety. DOE 6430.1 (latest issue), "General Design Criteria," provides a definition of safety class and examples of systems, structures, and components that are normally designated as safety class in DOE facilities. Safety Analysis Reports should exist for each DOE nuclear facility which define that facility's systems, structures, and components important to safety.

Designs should provide for appropriate inspection, testing, and maintenance to ensure continuing reliability and safety of the system, structure, or component. The design should consider the expected use and life expectancy of the system, structure, or component in order to address appropriate disassembly and disposal requirements.

Design records may include design input, calculations and analyses, engineering reports, design output documentation, design verification documentation, design change documentation, and design revisions.

6.2 Design Input

Design inputs should be technically correct and complete. These inputs may include such information as design bases, health and safety considerations, expected life cycle, performance parameters, codes and standards requirements, and reliability requirements. Technical design interfaces should be identified in the input documents and methods should be established for their control.

Administrative interfaces which include authorities, responsibilities, and lines of communication between the project team members should be defined in sufficient detail to identify and establish relationships of such team members as end-user, stakeholders, responsible design agency, designers, purchasing agents, suppliers, and testers/inspectors.

6.3 Design Process

The design process should translate design input into design output documents that are technically correct and meet the end-user's requirements. Aspects critical to the safety or reliability of the designed system, structure, or component should be identified during the design phase. Design output documents should be usable by other project processes such as: manufacturing, assembly, construction, testing, inspection, maintenance, and decommissioning.

Computer software used to originate or verify design solutions during the design process should be validated or the status of code validation should be identified and documented prior to use.

The agency accomplishing the design should verify that design output documents meet design input requirements and that any deviations have been approved and documented.

6.4 Design Output

The completed design should be recorded in design output documents such as drawings, specifications test/inspection plans, maintenance requirements, and reports. As-built drawings and shop drawings should be maintained after production or construction to show actual configuration. The administrative interface process should clearly indicate responsibilities for design output document activities including as-built mark-up and updating during project construction/production phases, media use and transmission, document control and records management.

6.5 Design Verification

Design verification is a formal documented process to establish that the resulting system, structure, or component will be fit for the intended use. Design verification methods include, but are not limited to, technical reviews, peer reviews, alternate calculations, and qualification testing. When appropriate, the verification process may take previous validations of similar designs or on similar features of other designs into account. The design verification process may be used to identify opportunities for improvements in the efficiency, productivity, safety, reliability, or cost of the designed system, structure, or component.

Design verification should be performed by technically knowledgeable persons separate from those who performed the design. Interim verifications may be made at predetermined stages of design development. The extent and number of design verifications should be based on a graded approach and should depend on the designed product's complexity and importance to project success.

Design verification should be completed before design output is used by other organizations or to support other work such as procurement, manufacture, construction, or experiment. When this timing cannot be achieved, the unverified portion of the design should be identified and controlled. In all cases, design verifications should be completed before relying on the system, structure, or component to perform its function and before installation becomes irreversible.

6.6 Design Changes

Design changes, including field changes and nonconforming items dispositioned "use-as-is" or "repair," should be controlled by measures commensurate with those applied to the original design. Temporary modifications should receive the same levels of control as the designs of permanent modifications.

6.7 Applicable Standards

The following consensus standards provide acceptable methods for implementing many of the requirements of Criterion 6; Although, some of the standards do not fully meet all of the requirements. The principles, recommended approaches, and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the development and implementation of an effective design and design change control system.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.4, "Design Control."

2. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements - Guidelines, Section 8, "Quality in Specification and Design."

3. DOE/RW/0333P, dated December 18, 1992 Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program, Section 3.0, "Design Control," and Supplement I, "Software."

4. NE F 1-2T, dated January 1, 1989, Preparation of plant and System Design Description Documents.

5. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirement 3, "Design Control," Supplement 3S-1, "Supplementary Requirements for Design Control," and Nonmandatory Appendix 3A-1, "Nonmandatory Guidance on Design Control."

6. ASME NQA-2-1989, Quality Assurance Requirements for Nuclear Facility Applications, Part 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications."

6.8 References

1. 10 CFR Part 50, Appendix A, General Design Criteria for Nuclear Power Plants.

2. NUREG 0856 (1983), Final Technical Position on Documentation of Computer Codes for High-Level Waste Management.

3. ANSI/ASQC Standard E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.6, "Use of Computer Hardware and Software," and Part C, Section 4.2, "Design of Systems."

7. PROCUREMENT

7.1 Introduction

The procurement process should ensure that items and/or services provided by suppliers meet the requirements and expectations of the end-user. The procurement process should be planned and controlled to ensure that the end-user's requirements are accurately, completely, and clearly communicated to the supplier; that the suppliers', designers', and end-users' requirements are met during the production phase; and that the proper product is delivered on time and maintained until use.

The stringency of procurement requirements should be commensurate with the importance of the purchased items or services to the project. Management controls exist for DOE procurements and subcontracts through applicable DOE Orders, Department of Energy Acquisition Regulations (DEARs) in 48 CFR Part 9, and Federal Acquisition Regulations (FARs) in 48 CFR Parts 1 to 99. Criterion 7 of 10 CFR Part 830.120 should not be interpreted to require the development of redundant procurement management systems, but rather to ensure that existing procurement management systems adequately response to end-user requirements.

7.2 Procurement Documents

The procurement documents should clearly state test/inspection requirements and acceptance criteria for purchased items and services. Procurement documents should include any specifications, standards and other documents referred to by the design documents. Critical parameters and requirements such as submittals, product related documentation, nonconformance requirements, administrative documentation, personnel or materials qualification, tests, inspections, and reviews should be specified as line items.

7.3 Supplier Qualification

Required qualified suppliers should be identified early in the design and procurements process. The prospective suppliers should be evaluated to verify their capability to meet performance and schedule requirements. The qualified suppliers should be evaluated periodically to confirm their continuing capabilities.

Measures for evaluating and selecting suppliers may include:

- a review of the supplier's history for providing identical or similar items or services;

- an assessment of the supplier's capability based on evaluation of its facilities, personnel, and programs; or

- an evaluation of documented qualitative and quantitative information provided by the supplier.

7.4 Supplier Monitoring

Required supplier monitoring should be performed during the procurement process to ensure that acceptable items or services and schedule requirements are being met. Monitoring may include:

- surveillance of work activities;
- inspection of facilities and processes;
- review of plans and progress reports;
- processing of change information; and
- review and disposition of nonconformances.

7.5 Nonconformance and Corrective Action

Some programs or projects may be required to establish a formalized process to document occurrences when purchased items or services do not meet specifications. This process should specify the roles and responsibilities of program/project participants to ensure that results of actions taken meet program/project requirements.

7.6 Inspection

The procurement system should include provisions for inspections. Requirements for inspections should be obtained from design documents. Inspections should be adequate to ensure conformance with purchase requirements including verifying that specified documentation has been provided by the supplier. The inspection should verify that items were not damaged during shipment. Inspection may include the following methods:

- inspections of materials or equipment at the supplier's plant;
- receipt inspection of the shipped items;
- review of objective evidence such as certifications and reports; and
- verification of testing of items prior to or following shipment.

The procurement system should include provisions for conducting testing activities that may be required during the procurement process.

7.7 Product Documentation

Supplier generated documents should be adapted through the procurement system and controlled and processed by the end-user organization according to the provisions of Criterion 4 (Documents and Records). These documents may include certificates of conformance, drawings, analyses, test reports, maintenance data, nonconformances, corrective actions, approved changes, waivers, and deviations.

7.8 Applicable Standards

The following consensus standards provide acceptable methods for implementing many of the requirements of criterion 7, although some of the standards do not fully meet all of the requirements. The principles and recommended approaches and applications contained in these standards may by used in conjunction with 10 CFR 830.120 in the development and implementation of an effective system for procurement management.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.6, "Purchasing," and Section 4.7, "Purchaser Supplied Product."

2. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements - Guidelines, Section 9, "Quality in Procurement."

3. DOE/RW/0333P, dated December 18, 1992 Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program, Section 4.0, "Procurement Document Control,:" and Section &.0, "Control of Purchased Items and Services."

4. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Basic Requirements 4, "Procurement Document Control," and 7, "Control of Purchased Items and Services," Supplements 4S-1 and 7S-1, and Appendices 4A-1 and 7A-1.

7.9 References

1. 48 CFR Parts 1 - 99 Federal Acquisitions Regulations System.

2. Electric Power Research Institute Guideline EPRI NP-5652, 1988 Revision, "Guidelines for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications."

3. IAEA Safety Guide 50-SG-QA3, to be issued, Procurement of Items and Services.

4. ANSI/ASQC Standard E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.4, "Procurement of Items and Services."

8.0 INSPECTION AND ACCEPTANCE TESTING

8.1 Introduction

Inspections/tests are accomplished to verify that physical characteristics and functions of systems, structures, and components are acceptable to the organization that will use the systems, structures, and components. Systems, structures, and components requiring inspection/test should be identified early in the design phase.

Inspections and tests should be conducted according to a graded approach. Acceptance parameters and other requirements such as inspection/test equipment or qualified inspection/test personnel should be specified in design documentation.

Systems, structures, and components should be ready for service at the conclusion of the inspection or test process. The types of systems, structures, and components and the length of time they are to remain in storage should be considered when generating the inspection or test plan.

The inspection/test process should identify the status of systems, structures, and components requiring examination to ensure that failed or untested systems, structures, and components are not used. A method should be developed which controls reinspection and retesting for previously failed systems, structures, and components. The methods should provide for review and documentation of changed inspection/test parameters.

Inspection/tests should be performed by technically qualified personnel that have the freedom of access and communication to report inspection/test results. Final acceptance of systems, structures, and components should be verified and documented by organization having the final responsibility for the systems, structures, and component.

8.2 Process

Inspection/test methods should be established that define the requirements for activities that verify conformance of systems, structures, and components with specified requirements. Results of these activities should be documented and retained as project records. Inspection/test activities should be performed by persons other that those who performed or directly supervised the work being examined.

Inspections/tests should be performed to written directives. Appropriate sections of approved codes or standards may be used for acceptance requirements and inspection/test methods in lieu of specially written test procedures. Inspection/test documentation should contain provisions for at least the following:

- identification of characteristics to be examined;
- required qualifications of individuals who perform the examination;
- a description of the examination methods including equipment and calibration requirements;
- acceptance and rejection criteria;
- required safety measures ; and
- action taken concerning any deviations noted.

Inspection/test results should be evaluated and verified by authorized personnel to document that all requirements have been satisfied. Records should, at a minimum, identify:

- Item tested;
- date of test;
- tester or data recorder;
- observations;
- results and acceptability; and
- action taken concerning any deviations noted.

8.3 Control of Measuring and Test Equipment

The inspection and acceptance testing methods should establish requirements for a calibration system to ensure that measuring and test equipment (M&TE) used to verify conformance to design requirements are of the proper type, range, accuracy, and are uniquely identified and traceable to their calibration data.

The method should ensure that adequate procedures for testing, retesting, adjusting, and re-calibration of M&TE are maintained and documented by organizations performing inspection and testing functions. When applicable, M&TE should be calibrated to standards traceable to the National Institute of Standards and Technology.

8.4 Applicable Standards

The following consensus standards provide acceptable methods for implementing many of the requirements of criterion 8, although none of the standards fully meets all of the requirements. The principles and recommended approaches and applications contained in these standards may by used in conjunction with 10 CFR 830.120 in the development of an effective inspection and acceptance program.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.10, "Inspection and Testing," Section 4.11, "Inspection, Measuring , and Test Equipment," and Section 4.12, "Inspection and Test Status."

2. ISO-9002-1987 (ANSI/ASQC Q92-1987), Quality Systems - Model for Quality Assurance in Production and Installation, Section 4.5, "Inspection and Testing," Section 4.6, "Inspection, Measuring , and Test Equipment," and Section 4.7, "Inspection and Test Status."

3. ISO-9004-1987 (ANSI/ASQC Q94-1987), Quality Management and Quality System Elements-Guidelines, Section 11.7, "Control of Verification Status," Section 12, "Product Verification," and Section 13, "Control of Measuring and Test Equipment."

4. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Section 10, "Inspection," Section 11, "Test Control," Section 12, "Control of Measuring and Test Equipment," Supplements 10S-1, 11S-1, and 12S-1.

   NOTE: Supplements 2S-1, 2S-2, and 2S-3; and Nonmandatory Appendices 2A-1 and 2A-3 contain useful capability standards for inspection and test personnel.

5. ASME NQA-2-1989, Quality Assurance Requirements for Nuclear Facility Applications, Part 2.16, "Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities."

6. MIL-STD-45662A, Calibration System Requirements, June 10, 1980; Revision A, August 1, 1988.

8.5 References

1. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research, Page 11.

2. American Society for Nondestructive Testing Standard ASNT-TC-1A.

   NOTE: Contains capability standards for NDT/NDE personnel.

3. NUREG 1293, Revision 0, dated January 1989, Quality Assurance Guidance for Low Level Waste Disposal Facility, Section 10, "Inspection," and Section 11, "Test Control."

4. MIL-I-45208A, Inspection System Requirements, December 29, 1960; Revision A, December 16, 1963.

5. IAEA Safety Guide 50-SG-QA-13, to be issued, Inspection and Testing.

9. MANAGEMENT ASSESSMENT

9.1 Introduction

Managers at every level should periodically assess the performance of their organization to determine how well leadership is being provided to enable the organization to continuously meet the customer's requirements and expectations. This assessment should place emphasis on the use of human and material resources to achieve the organization's goals and objectives. The management assessment should include an introspective evaluation to determine if the entire integrated management system effectively focuses on meeting strategic goals. Criteria set forth in the Presidential Award for Quality, the Malcolm Baldridge National Quality Award, or the Quality Improvement Prototype Award may be used as a basis for management assessments.

9.2 Responsibility

Managers should retain overall responsibility for management assessments. Direct participation by managers is essential to the success of the process since management is in the position to view the organization as a total system.

9.3 Process

Management assessments should focus on the identification and resolution of both systemic and cultural management issues and problems. Strengths and weaknesses affecting the achievement of organizational objectives should be identified so that meaningful action can be taken to improve quality.

Processes being assessed should include strategic planning, organizational interfaces, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support. Effective management assessments should evaluate such conditions as the state of employee knowledge, motivation, and morale; the amount of mutual trust and communication among workers; the existence of an atmosphere of creativity and improvement; and the adequacy of human and material resources.

Direct observation of work is an effective method of management assessment. It provides the assessor with awareness of all interactions at a work location. Other methods of assessment are most effective when combined with work observation. These methods include interviews of workers, reviews of documentation, and conduct of frills or exercises.

9.4 Results

Management assessment results should be used as input to the organization's continuous improvement process.

9.5 Applicable Standards

The following consensus standards provide acceptable methods for implementing many of the requirements of Criterion 4. Note that no single standard may fully meet all of the requirements. The principles and recommended approaches and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the development of an effective management assessment program.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.17, "Internal Quality Audits."

2. DOE-ER-STD-6001-92, dated June 1992, Implementation Guide for Quality Assurance Programs for Basic and Applied Research, Part II.C, Criterion 9, "Management Assessment."

9.6 References

1. DOE Student Training Manual, dated February 10, 1993, Management Assessment Training.

2. ASQC Energy Division, Quality Surveillance Guidelines and Quality Surveillance Handbook, ASQC Quality Press, 1992.

3. NUREG/CR-5151, dated February 1989, Performance-Based Inspections.

4. DOE/EH-135, dated June 1990, performance Objectives and Criteria for Technical Safety Appraisals at Department of Energy Facilities and Sites.

5. Presidential Award for Quality, Federal Quality Institute.

6. Quality Improvement Prototype Award, Federal Quality Institute.

7. Malcolm Baldridge Award, National Institute for Standards and Technology.

8. IAEA Safety Guide 50-SG-QA10, to be issued, Assessment.

9. ANSI/ASQC E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.9, "Quality Assessment and Response."

10 INDEPENDENT ASSESSMENT

10.1 Introduction

Management should establish and implement a method for independent assessment of organizations, programs and projects in order to evaluate the performance of work processes with regard to requirements and expectations of customers and toward achieving the mission and goals of the organization. The independent assessment process should use a performance-based approach with emphasis on results and with compliance viewed as the baseline. Assessments should be conducted on activities that most directly relate to final objectives and should emphasize safety, reliability, and product performance Independent assessments may include such methods as inspections, peer and technical reviews, audits, surveillances, or combinations thereof.

10.2 Performing Organization

The assessing organization should advise management and should report to a sufficiently high level in the overall organization to ensure organizational independence and access to appropriate levels of authority. Personnel performing independent assessments should have the necessary technical knowledge to accurately observe and evaluate activities being assessed. Personnel performing assessments should not have direct responsibilities in the areas they are assessing and should consider the organizations being assessed as customers for feedback concerning observations of performance.

10.3 Process

The types and frequencies of independent assessments should be based on the status, complexity, and importance of the activities or processes being assessed. The criteria used for assessments should describe acceptable work performance and should promote improvement of the process or activity. Assessments should also address management processes which affect work performance such as planning, program support, and training.

Personnel performing assessments should focus on improving output quality and process effectiveness by emphasizing continuous improvement methods. Assessment personnel should not reinterpret or redefine the requirements specified in approved programs The assessors' responsibilities include:

- evaluating work performance and process effectiveness;
- identifying abnormal performance and potential problems;
- finding opportunities for improvements:
- documenting and reporting results; and

- verifying satisfactory resolutions of reported problems.

The independent assessment process should include verification of the adequacy of corrective actions, including actions identified to prevent recurrence or to otherwise improve performance.

10.4 Results

Assessment results should be documented, presented to the organization that was assessed, and provided to the appropriate levels of management for review. Strengths and weaknesses affective the quality of process outputs should be identified so that meaningful action can be taken to improve quality.

Independent assessments which verify good performance in some or all areas of an organization may result in a reduction in the frequency and depth of future assessments. Areas of poor or questionable performance should receive increased attention.

Lessons learned from the assessment process should be communicated to other organizations with similar activities or concerns. Identified action items should be tracked for resolution and evaluated to determine whether similar deficiencies exist elsewhere.

10.5 Applicable Standards

The following consensus standards provide methods for implementing many of the requirements of Criterion 10. No single standard fully meets all of the requirements. The principles and recommended approaches and applications contained in these standards may be used in conjunction with 10 CFR Part 830.120 in the development of an effective Independent assessment program.

1. ISO-9001-1987 (ANSI/ASQC Q91-1987), Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing, Section 4.17, "Internal Quality Audits."

2. DOE/RW/0333P, dated December 18, 1992 Quality Assurance Requirements and Description, Section 18.0, "Audits."

3. ASME NQA-1-1989, Quality Assurance Program Requirements for Nuclear Facilities, Section 18, "Audits," Supplement 18S-1, "Supplementary Requirements for Audits," and Appendix 18A-1, "Nonmandatory Guidance on Audits."

10.6 References

1. ASQC Energy Division, Quality Surveillance Guidelines and Quality Surveillance Handbook, ASQC Quality Press, 1992.

2. NUREG/CR-5151, dated February 1989, Performance-Based Inspections.

3. DOE/EH-135, dated June 1990, Performance Objectives and Criteria for Technical Safety Appraisals at Department of Energy Facilities and Sites.

4. IAEA Safety Guide 50-SG-QA10, to be issued, Assessment.

5. ANSI/ASQC E4-19XX, to be issued, Quality Systems Requirements for Environmental Programs, Part A, Section 2.9, "Quality Assessment and Response."